Gail Vasterling

Director



FAX: 573-751-6010

Jeremiah W. (Jav) Nixon Governor

Dear Initial Applicant for Licensure as an Ambulatory Surgical Center (ASC):

In response to your request, the Bureau of Ambulatory Care (BAC) is providing you information relative to the licensing of a new Ambulatory Surgical Center (ASC). Initial planning for your facility will need to (1) assure conformity with any applicable Certificate of Need (CON) laws/regulations as found at: http://health.mo.gov/information/boards/certificateofneed/laws.php. The CON Program can be contacted by phone at 573-751-6403 or by email at CONP@health.mo.gov.

Further, the facility must be designed, constructed and equipped from plans that have been reviewed and approved by the Department of Health and Senior Services Engineering Consultation Unit (ECU) as being in compliance with all applicable standards established in 19 CSR 30-30.030 and 19 CSR 30-30.040.

You should begin by reviewing and becoming familiar with all applicable requirements under state licensure rules, which can be found at: http://www.sos.mo.gov/adrules/csr/current/19csr/19c30-30.pdf

General steps in the licensure process, all of which must be completed prior to issuing a license:

- 1. Review and approval of plans from the ECU unit and subsequent onsite construction reviews. Contact with the ECU should be one of, if not your very first step in the process. Contact the ECU by phone at 573-526-8521, or you may contact the ECU director David East by email at David. East@health.mo.gov
- 2. Submission of ASC application, fee, and addendum to the Bureau of Ambulatory Care.
- 3. Ensure the facility has applied for and received applicable registrations from the Bureau of Narcotics and Dangerous Drugs (BNDD) and DEA to order narcotics. BNDD can be contacted at 573-751-6321. For more information about BNDD see http://health.mo.gov/safety/bndd/
- 4. Ensure the facility has applied for and received a certificate to perform laboratory testing from the Clinical Laboratory Improvement Act (CLIA) program. The CLIA lab program can be contacted at 573-751-6318. For more information see http://www.health.mo.gov/safety/outpatienthealthcare/index.php
- 5. Onsite initial licensure survey to obtain a license to operate as an ASC must be successfully completed before patient care may be offered. The facility must ensure all components to provide patient care are in place and ready to deliver patient care, including but not limited to medications, policies, orientation of staff and all equipment are in place. Again, an onsite initial state licensure survey to ensure compliance with all applicable licensure regulations must occur prior to providing services to any patient.

As the facility nears completion, the license application must be completed, signed and notarized, and returned to the Bureau of Ambulatory Care with complete documentation as indicated on the attachments and accompanied by the required annual licensing fee of \$200. Please make checks payable to the Department of Health and Senior Services. The licensure application is to be submitted at least thirty (30) days before the date of the planned initial survey may be found at http://health.mo.gov/safety/asc/pdf/AmbulatorySurgicalCenterLicenseApplication.pdf

The application is to be accompanied by:

- Appropriate documentation to establish that the applicant is legally entitled to do business in this state and has filed with the Office of Secretary of State. A current business license should also be available for review at the facility and the facility must be in compliance with all local ordinances.
- List of key staff persons for the facility with email and phone for the administrator:
- Governing board meeting minutes that show when permission to establish an ASC was given.
- List of the intended surgical specialty types and the projected average length of time for the typical surgical procedure to include recovery from anesthesia.

Facilities planning on participating in the Medicare program as an ASC must meet the initial requirements of the application process. You may request this packet of information from our office if you wish to start the Medicare certification process or obtain them from your choice of accreditation organization.

Please note: Centers for Medicare and Medicaid (CMS) considers initial federal ASC certification surveys a low priority for the State Agency's workload. This means it is unlikely that the state agency will be able to perform the initial federal certification. For this reason, an ASC seeking certification is strongly urged to pursue a *deemed status survey* through an approved Accreditation Organization (AO). Contact our office if you need additional information about this process or which AO's you can contact.

In order to facilitate an orderly opening, please keep our office up to date on when the facility will be nearing completion and have all supplies, medications, and equipment in place to be fully operational to schedule the initial licensure survey. Notify our office when construction starts with an anticipated completion date. When the facility is nearing completion routine updates are requested to notify us of any change in the projected completion date. If there are significant changes to any of the dates please inform our office. Contact by email is adequate for these updates.

If you have any questions regarding the Medicare or state regulations, please contact our office at (573) 751-6083 or via email at BAC@health.mo.gov The Bureau will make every effort to assign high priority to your application. However, to be successful, your cooperation in the matter is required.